

2. **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 6-8, 10 and 11 are to be cancelled.

Claim 9 is amended presently.

Claim 12 is added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are or were in the application is presented, irrespective of whether the claim(s) remain under examination in the application, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 9 and 12 are now pending in this application.

Priority

Applicants submitted to the PTO on June 13, 2003, an English translation of priority application 51234/1995, filed in Japan on March 10, 1995. Accordingly, the latter date should be the effective filing date of the pending claims.

Drawings

Along with this Amendment, Applicants submit formal drawings as requested by the Examiner on page 3 of April 24, 2003 Office Action.

Objection to the Abstract

As suggested by the Examiner on page 3 of the Office Action dated April 24, 2003, Applicants propose to revise the Abstract to remove reference to SEQ ID NOs and to include the full name of the enzyme, isopentenyl pyrophosphate (IPP) isomerase, as well as example source species. This Amendment will allow others to search patent databases, including foreign databases, by the Abstract. Please replace the previously submitted Abstract with the new

Abstract presented at the end of this Amendment, to be inserted after the claim pages of the application.

Objection to the Title

The Examiner objected to Applicant's title of the specification, and suggested a new title further reflecting the pending claims. Please amend the title at line 1, page 1 of the specification as follows:

~~A DNA chain useful for increasing production of carotenoids~~ DNA Molecules Encoding Polypeptides Having Isopentenyl Pyrophosphate Isomerase Activity and Methods for Producing Cartotenoids Using the Same

Objection to the Claims

As suggested by the Examiner on page 4 of the April 24, 2003 Office Action, Applicants are amending claim 9 to recite "carotenoid-producing microorganism" to properly modify the noun of the phrase. Claims 10 and 11 are canceled.

Rejection under 25 U.S.C. §112, first paragraph (written description requirement)

On page 4-5 of the April 24th Office Action, the Examiner rejects pending claim 9, asserting a lack of adequate written description of the claimed genus. The Examiner contends in particular that the specification discloses single examples of IPP isomerase-encoding DNA from three different species and that the skilled person, so informed, would be unable to predict the structure of other genus members.

Claim 9 recites "a DNA molecule containing a nucleotide sequence that encodes a polypeptide having an IPP isomerase activity." Applicants respectfully submit that claim 9 in its entirety is described in the specification in such a way as to convey to those skilled in the art that the inventors had possession of the claimed invention at the time of filing.

In making a new rejection under the written description requirement, the Examiner relies on the Federal Circuit decision, *University of California v. Eli Lilly*, 119 F.3d 1559 (Fed. Cir.

1997). The *Eli Lilly* case related to claims that recited either “human insulin cDNA” or a genus such as “vertebrate insulin cDNA.” Because the specification at issue in that case only disclosed one species (rat) of insulin cDNA and a description of human insulin A and B amino acid sequences, the court found that the specification did not provide a written description of human insulin cDNA. *Eli Lilly*, 119 F.3d at 1567-68. As explained in *Eli Lilly*, however, “every species in a genus need not be described in order that a genus meet the written description requirement. *Id.* at 1568, citing *Utter v. Hiraga*, 845 F.2d 993, 998-99. Moreover, a “description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.” *Id.* at 1569.

Several recent Federal Circuit decisions have addressed the holding of *Eli Lilly*. In *Enzo Biochem v. Gen Probe*, for instance, the court clarified that *Eli Lilly* did not indicate “that all functional descriptions of genetic material fail to meet the written description requirement.” 323 F.3d 959, 964 (Fed. Cir. 2002). Instead, the written description requirement “may be satisfied if in the knowledge of the art function is sufficiently correlated to a particular known structure.” *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313, 1332 (Fed. Cir. 2003), discussing *Enzo* and *Eli Lilly*, *supra*. In *Enzo* the court considered whether the written description requirement was met for the claims on the basis of the functional ability of the claimed nucleotide sequences to hybridize to three strains of *N. gonorrhoeae* accessible by deposit. 323 F.3d at 964. The court explained that, if “those [three deposited] sequences are representative of the scope of the genus claimed, i.e., if they indicate that the patentee has invented species sufficient to constitute the genera, [then] they be representative of the scope of those claims.” *Id.* at 967.

Applicants’ specification does not simply disclose one DNA sequence encoding IPP isomerase activity and, hence, is unlike the disclosure of only one (rat) cDNA sequence coding insulin, as in *Eli Lilly*. Rather, the specification describes at least three different DNA sequences encoding IPP activity, each from a different species. For example, see pages 24 and 35-39 (SEQ ID NOs 4 and 5), which disclose IPP isomerase genes derived from *Phaffia rhodozyma* and *Haematococcus pluvialis*, and page 26, lines 1-23, pages 39-41 (SEQ ID NO 6), disclosing a IPP

isomerase gene derived from *Saccharomyces cerevisiae*. Thus, the specification discloses a representative number of DNA sequences, each defined by a different nucleotide sequence, that falling within the scope of the genus of “DNA molecule[s] containing a nucleotide sequence that encodes a polypeptide having an IPP isomerase activity.”

In addition, the present specification teaches that the inventors identified *Phaffia rhodozyma* and *Haematococcus pluvialis* DNA sequences as IPP isomerase genes by comparing isolated sequences to the IPP isomerase gene of *Saccharomyces cerevisiae*. Application, page 24, line 28 – page 25, line 3. Accordingly, those skilled in the art understood that the specification described at least one structural feature common to members of the genus, i.e., DNA molecules having substantial homology to the disclosed IPP isomerase genes of *Phaffia rhodozyma*, *Haematococcus pluvialis* or *Saccharomyces cerevisiae*. See the application at page 24, line 28 – page 25, line 3.

The specification also discloses that the inventive category of DNA molecules, as claimed, includes: (1) DNA molecules that increase carotenoid production by virtue of containing a nucleotide sequence coding for a primary amino acid sequence substantially similar to SEQ ID NOs 1-3; and (2) DNA molecules that can hybridize with the disclosed IPP isomerase DNA sequences (SEQ ID NOs 4-6). See application at page 6, line 10 – page 7, line 5. Those skilled in the art would understand, therefore, that the specification describes, for the recited genus, two additional features drawn to primary structure (1) and DNA structure (2), both of which reasonably correlate with IPP isomerase activity, i.e., an activity to convert IPP to DMAPP.

In sum, Applicants’ specification discloses a representative number of DNA molecules, defined by nucleotide sequences, falling within the scope of the genus, as well as at least three structural features common to a substantial portion of the genus. *See Eli Lilly*, 119 F.3d at 1569. Thus, the specification provides adequate written description of the recited DNA molecules of the claims.

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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